Statement of Rep. Henry A. Waxman
GPhA Annual Meeting
February 19, 2014

I am pleased to join you today, even if only by video, as we commemorate the 30th anniversary of the Waxman Hatch Act. I always look forward to opportunities to applaud the generic drug industry for its tremendous work in bringing safe, effective, and low-cost drugs to American consumers, and to the world over.

Who would have dreamed in 1984, when we passed the legislation, that thirty years later well over eighty per cent of all U.S. prescriptions would be filled by generics? Or that the use of generic medicines would be saving the American healthcare system over $200 billion a year.

Yet despite these undisputable benefits to the American public, the industry is again under attack, much as it was before passage of the legislation.

Back then, the generic drug industry was in severe decline. The 1962 Amendments to the drug law required that manufacturers demonstrate that their drugs were not only safe, but also were effective. FDA interpreted this requirement to mean that generic drug manufacturers had to conduct full clinical trials on drugs that had already been shown by the brand manufacturer to be safe and effective. These trials were not only unnecessary, they were effectively a death knell for generic manufacturers. Yet many in Congress were focused only on helping the brand industry, offering legislation that would have provided patent term restoration for the time expended in meeting the 1962 requirements.

In the end, we passed balanced legislation, which supported both innovation and competition. However, now again, as patents on many blockbusters are expiring, there are those focusing only on the wish list of the brands.

For example, there is legislation in Congress that would extend exclusivity, with the ostensible purpose of stimulating development of drugs for unmet medical

needs. However, the brand industry has a long history of finding new rationales for advancing their ultimate goal of maintaining monopoly control over their products for as long as possible.

There is legislation in states around the country that would require pharmacists to notify doctors any time they provide a patient with an interchangeable biosimilar. I fear that these laws are not designed to facilitate transparency, but to discourage the use of interchangeable biosimilars. It is worth remembering that in the early 1980s, before state laws facilitated routine generic substitution at pharmacies, brands often maintained 85% to 95% market share of their most valuable drugs even when much cheaper generic versions were available.

I am also concerned about the growing practice of brand manufacturers preventing generic manufacturers from obtaining samples of drugs they need to conduct the testing necessary for approval. For example, a manufacturer may claim it cannot provide the drug because it would violate a REMS, with no evidence that FDA concurs. Such practices enable companies to prolong their monopoly control over drugs.

And we must remain vigilant that our trade agreements don't delay access to generic medicines in developing countries.

So, we still have challenges. But this is an occasion to celebrate the great success of the generic drug industry in lowering healthcare costs and stimulating innovation. With GDUFA, FDA finally has the resources it needs to eliminate the backlog of old applications and speed up approvals of new applications. With the biosimilar legislation that was part of the Affordable Care Act, we finally will have competition for biologics, albeit with an overly long period of exclusivity. But with that Act, and with the fees from BSUFA, FDA is creating a workable pathway for biosimilars.

As all of you know, the availability of high quality generic drugs is one of the most effective ways to hold down the costs of health care. That is why I will

continue to work to promote competition and innovation in our prescription drug industry and to increase the use of generic medicines worldwide.

I applaud all of you for the work you do every day to achieve this goal. And I thank you for this opportunity to speak with you.